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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/673,341	10/13/2000	Hisakazu Kurita	K0448/7003	5123

7590 12/31/2003

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EXAMINER	
GHALI, ISIS A D	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 12/31/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/673,341	KURITA ET AL.	
	Examiner	Art Unit	
	Isis Ghali	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 October 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 1-12 are included in the prosecution.

Claim Rejections - 35 USC § 103

The Standing Rejection:

Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over any of US 4,740,374 ('374) and US 5,866,157 ('157), each by itself or in combination with US 5,271,946 ('946).

US '374 teaches an adhesive composition for percutaneous absorption comprising alkaline salt of the drug (basic salt) and organic acid such as acetic acid. The amount of the drug salt is from 1 to 40 % and the amount of the organic acid is from 10 to 50 % (abstract; col.2, lines 30-33; col.3, lines 67-68; col.4, lines 1-4, 57, 62; col.9, lines 12-15).

US '157 teaches an adhesive composition for matrix patch formulation comprising from 0.1 to 20 % (w/w) of a basic drug and from 0.01 to 15 % (w/w) of organic acid or its salt such as sodium acetate (abstract; col.2, lines 40-60; col.3, lines 9-25, 55-58; examples).

However, US '374 and US '157 do not disclose the organic acid in the powder from or the mean diameter of the powder particles.

US '946 teaches a pharmaceutical composition comprising sodium acetate having a particle size of about 0.1 to 200 micrometer used for as oral and topical composition in an amount of 5-70 % (col.3, lines 10-33; col.4, lines 38-41; col.6, lines 58-62). The dosage form of the composition include plaster (col.3, line 24). The composition comprising the sodium acetate having this particle size provides controlled release of the active substance (abstract).

Thus, it would have been obvious to one having ordinary skill in the art at he time of the invention to provide percutaneous composition comprising a base drug salt and an organic acid salt as disclosed by any of US '347 and US '157, and replace the organic acid salt by sodium acetate as disclosed by US '946, motivated by the teaching of US '947 that the composition comprising the sodium acetate having this particle size provides controlled release of the active substance, with reasonable expectation of having a controlled release percutaneous composition.

Applicants' arguments:

Applicant provides results demonstrating criticality of the particle size in an adhesive preparation containing base drug as the salt form improves solubility of the drug. The cited prior art US '374 and US '157 do not teach that the organic acid salt in the form of powder or the specific mean diameter that improves the skin permeability of the drug. US '946 teaches the sodium acetate as pore forming agent . US '947 does not teach percutaneous absorption preparations. No motivation to combine the teachings of US '374 or US '157 with US '946.

***Response to Arguments*:**

Applicant's arguments above have been fully considered but they are not persuasive.

The results provided by applicant show excellent absorbance of the drug with particle size of 0.1 to 10 micrometer, while the claims recite up to 100 micrometer. Furthermore, applicant did not show the effect of particle size out side the claimed range, i.e. below 0.1 and above 100. The comparative examples of record used the un-grounded sodium acetate, i.e. the crystals and not the powder. The art recognized the suitability of the sodium acetate in increasing the dermal absorbability of active agents. Both of US '374 and US '157 disclose the combination of base drug and organic acid salt in an adhesive preparation for percutaneous administration, as claimed by the applicants. The references are silent regarding the state of sodium acetate, and that does not exclude its presence as a powder. Sodium acetate is a known as powder; see the "Condensed Medial Dictionary", page 1007, 1008. Applicants failed to show superior and unexpected results that show criticality in the claimed particle sizes. Both references teach that the presence of sodium acetate in the preparation for the same purpose desired by applicants, that is improved percutaneous absorption, see US '374, col.4, lines 47-50, and US '157, col.2, lines 32-39. It is within the skill in the art to determine the diameter of the particle in order to achieve a beneficial effect. Each of the cited references teaches percutaneous preparation; see US'374 abstract and col.2, lines 30-31; US 157 col.2, lines 23-29; US '946 col.3, line 24. US '374 and US '157 can

stand each by itself, without combination with US '946. US '946, if relied upon, it is relied upon for the solely teaching of the size of the sodium acetate particles and its use in topical and oral pharmaceutical compositions. US '946 teaches that the composition comprising the sodium acetate having this particle size provides controlled release of the active substance. Thus, it would have been obvious to one having ordinary skill in the art to provide a composition comprising a base drug and an organic acid salt in the form of a powder and select the particle size of the powder that required to achieve the desired rate of permeation across the skin, with reasonable expectation of having a controlled release percutaneous composition.

Conclusion

1. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

2. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (703) 305-4048. The examiner can normally be reached on Monday through Thursday from 7:00 AM to 5:30 PM, Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)305-1235.

Isis Ghali
Examiner
Art Unit 1615

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600